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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,169	10/26/2000	Rudolf Valenta	1614-244P	4340

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/696,169	VALENTA ET AL.	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/26/00; 6/8/01; 9/13/01; 10/4/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13 and 14* is/are pending in the application.

4a) Of the above claim(s) *7-11 and 13-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-11 and 13-14 are pending.

2. Applicant's election with traverse of Group I, claims 1-6 that read on a hypoallergenic immunogenic molecule derived from Phl p6 allergen, filed 9/19/01, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The request of rejoinder of method claims 7-11 and 13-14 in view of In re Ochiai is acknowledged.

3. Claims 7-11 and 13-14 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claims 1-6 drawn to a hypoallergenic immunogenic molecule derived from Phl p6 allergen are being acted upon in this Office Action.

5. Applicant should amend the first line of the specification to reflect the relationship between the instant application and 60/164,148, filed 11/08/99.

6. The drawings, filed 10/26/00, are not approved. Please see enclosed PTO 948, Notice of Draftsperson's Patent Drawing Review. Appropriate action is required.

7. The reference Ebner et al on PTO 1449, filed 3/12/01 has been considered to the extend of the abstract only.

8. The following order or arrangement is preferred in framing the specification and, except for the title of the invention; each of the lettered items should be preceded by the headings indicated below.

   (a) Title of the Invention.
   (b) Cross-References to Related Applications (if any).
   (c) Statement as to rights to inventions made under Federally-sponsored research and development (if any).
   (d) Background of the invention.

1. Field of the Invention.
2. Description of the Related Art including information disclosed under *37 C.F.R. §§ 1.97-1.99.*

(e) Summary of the Invention.
(f) Brief Description of the Drawing.
(g) Description of the Preferred Embodiment(s).
(h) Claim(s).
(i) Abstract of the Disclosure.

9. The disclosure is objected to because of the following informalities: (1) "Threehundred" on page 5, line 23 should have been "Three hundred"; (2) "aminoacid" on page 12, line 13 should be "amino acid".

10. Claim 3 is objected to because "the" is recited twice in the claim.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that a full-length sequence of recombinant Phl p6 allergen is required to practice the instant invention. There is no disclosure in the specification as to the full-length amino acid sequence of recombinant Phl p6 allergen. Furthermore, there is no guidance in the specification as to which amino acid residues within the full-length amino acid sequence (polypeptide) can be deleted and whether after deletion at the unspecified residues would make the Phl p6 molecule "at least substantially lacks IgE binding capacity". Given the lack of a structural sequence to the Phl p6 allergen molecule, one of skilled in the art would not be able to practice the claimed invention based on the disclosure of the specification.

Although the specification discloses only six cDNA clones (c142, c223, c172, c233 and c146) of Phl p6, there is insufficient guidance about structure and function of any "clone" since the full length amino acid sequence is not provided in the specification as filed. Furthermore, only N-terminal truncated rPhl p6 aa 1-57, rPhl p6 aa 31-110 and rPhl p6 aa 1-33 have reduced IgE binding, and the capacity to induce histamine release in granulocytes from a patient allergic

to grass pollen for diagnostic assays (See page 13 of the specification). As exemplified in rPhl p6 aa 1-33 having N-terminal deletion, not all deletion makes the molecule "substantially lack IgE binding".

Mohapatra *et al* teach that although the potential of peptide treatment in downregulation of IgE antibody, given that some of the major allergens, particularly pollen allergens containing a number of T cell epitopes and that allergic individual differ with respect to their recognition of these epitopes, the success of this approach in presensitized individuals is difficult to predict (See page 42, first column, 1st paragraph, in particular). Given the indefinite number of hypoallergenic immunogenic molecule, it is unpredictable as to which Phl p6 molecule having an "N-terminal deletion" or a "C-terminal deletion" would be "at least substantially lack IgE binding capacity" and will be useful for hyposensitization immunotherapy for grass pollen allergy. Since the amino acid sequence is unknown, it follows that the immunogenic molecules derived from the Phl p6 allergen having N-terminally truncated, or C-terminally truncated which is produced by recombinant techniques or by peptide synthetic chemistry are not enable.

For these reasons, the specification as filed fails to enable one skill in the art to practice the invention without undue amount of experimentation. As such, further research would be required to practice the claimed invention.

13. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) *any* hypoallergenic immunogenic molecule derived from the Phl p6 allergen wherein the Phl p6 molecule has N-terminal and/or C-terminal deletion which makes the molecule at least substantially lack IgE binding capacity, (2) *any* Phl p6 molecule is N-terminal truncated, (3) *any* Phl p6 molecule is C-terminally truncated, (4) *any* immunogenic molecule mentioned above which is produced by recombinant technique, (5) *any* immunogenic molecule mentioned above produced by peptide synthetic chemistry, (6) *any* hypoallergenic immunogenic combination molecules derived from the Phl p6 allergen comprising any Phl p6 molecule having an N-terminal deletion which makes the molecule at least substantially lack IgE binding capacity, and any Phl p 6 molecule having a C-terminal deletion which makes the molecule at least substantially lack IgE

binding capacity which two molecules together encompass the complete sequence of Phl p6 for hyposensitization immunotherapy.

Although the specification discloses only six cDNA clones (c142, c223, c172, c233 and c146) of Phl p6, there is insufficient written description about structure and function of any "clone" since the full length amino acid sequence is not provided in the specification as filed. There is insufficient written about any molecule "at least substantially lack IgE binding capacity" since the term "substantially" is not defined in the specification.

With the exception of the specific N-terminal truncated rPhl p6 aa 1-57, rPhl p6 aa 31-110 and rPhl p6 aa 1-33 mentioned above, there is insufficient written description about the structure associated with function of any clone, any hypoallergenic immunogenic molecule derived from the Phl p6 allergen wherein the Phl p6 molecule is N-terminal truncated, or C-terminal truncated. Given only three N-terminal truncated Phl p6 molecules, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.* Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

15. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "substantially" in claims 1 and 6 is indefinite and ambiguous. ". It is unclear what are the metes and bounds of the term "substantially".

The "encompass the complete sequence of Phl p6" recited in claim 6, last line is improper because the complete sequence of Phl p6 does not contain any deletions.

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Petersen *et al* (Int Arch Allergy Immunol 108: 49-54; 1995; PTO 892).

Petersen *et al* teach two less immunogenic molecules derived from Phl p6 allergen wherein the Phl p 6 molecule has C-terminal deletion which makes the molecule at least substantially lack IgE binding capacity (See page 52, Fig 2, See page 53, right column second full paragraph, Fig 4, lane 4 and 5, band 13 kD, page 53, column 1, first full paragraph, in particular). The referenced molecule derived from Phl p6 allergen is the same as claimed molecule since the recitation of a process limitation in claims 4 and 5 do not further limiting the claimed product and the equivalent products can be obtained by various methods. Thus, the reference teachings anticipate the claimed invention.

18. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/34826 (July 1999, PTO 892).

The WO 99/34826 publication teaches hypoallergenic immunogenic molecules derived from Phl p6 allergen wherein the Phl p6 molecules have an N-terminal deletion or truncated (See page 65, lines 20-26, page 66, line 1-15, in particular) and a C-terminal deletion or C-terminally truncated (See page 24 line 26 bridging page 25, line 1, in particular). The WO 99/34826 publication teaches a composition containing a plurality of said reference molecules (peptides) (See page 8, lines 25-26, in particular) for desensitizing a patient to said peptides allergen. The lack of IgE binding capacity is one of the inherent properties of the modified reference molecules since the reference peptides are used for desensitized a patient. The publication further teaches the reference molecule is produced by peptide synthetic chemistry (page 47, lines 26-28, in particular). Claim 4 is included in this rejection because the referenced molecule derived from Phl p6 allergen is the same as claimed molecule since the recitation of a process limitation in claim 4 do not further limiting the claimed product and the equivalent products can be obtained by various methods. The publication further teaches a composition comprising a plurality of peptides which is a combination of peptides having N-terminal deletion or C terminal deletion

which make the molecule at least substantially lack IgE binding for desensitization therapy (See abstract, in particular). Thus, the reference teachings anticipate the claimed invention.

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

21. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

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December 3, 2001

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